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PATENT & TRADEMARK OFFICE

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Rana et al.

Application No.: 09/972,016

Filed: October 4, 2001

For: SITE-SPECIFIC PROTEIN MODIFICATION

Confirmation No.: 2378

Examiner: David Lukton

Group Art Unit: 1653

Docket: 1368-9 (267.302)

Dated: May 21, 2004

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postpaid in an envelope, addressed to: Commissioner for Patents, Alexandria, VA 22313

Dated: May 21, 2004

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Commissioner for Patents
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RESPONSE TO ELECTION OF SPECIES REQUIREMEMT

Sir:

This is in response to the Office Action mailed April, 23, 2004, a reply to which is due May 23, 2004.

The Examiner has acknowledged applicants' previous election of Group IV, with traverse. The Examiner has further acknowledged applicants' previous attempt to comply with the election of species requirement. Applicants elected a Tat protein as the specific modified protein that is labeled with a donor dye for the "first specie" for Group IV, and a fluorophore as a specific acceptor dye for the "second specie" for Group IV. However, in the Office Action mailed April 23, 2004, the Examiner alleges that applicants are non-responsive to the election of species requirement, and states the following:

What is required is identification of species as follows:

(a) a specific "modified protein" that bears a specific donor dye molecule. The modified protein should be identified with sufficient specificity so that the total number of amino acids is clearly evident, the sequence of amino acids is clearly evident, the position (in the sequence) of the "analog of the amino acid" is clearly evident, and the point(s) of attachment of the donor dye molecule is clearly evident along with any linking group that links the donor dye molecule with the "modified protein".

(b) a specific "donor dye molecule" with a fully defined structure such that every atom in the molecule is accounted for; and

(c) a specific "acceptor dye molecule" with a fully defined structure such that every atom in the molecule is accounted for.

Respectfully, Applicants fail to understand how the Examiner can hope to perform a meaningful search to the present invention by limiting the search to such a specific embodiment. As previously stated, the method of Group IV can employ any protein that has been modified by replacement of an amino acid with an amino acid analog at a site other than a lysine or cysteine residue. Therefore, restriction to a specific protein does not appear to be proper.

Moreover, as stated in applicants' specification at p. 10, lines 20-23, the donor is a fluorophore, while the acceptor dye is usually a fluorophore, although it does not have to be. The donor molecule transfers fluorescence energy to the acceptor molecule. All that is required of the donor/acceptor combination is that they are capable of participating in detectable fluorescence energy transfer with each other. Therefore, restriction to a specific donor dye molecule and a specific acceptor dye molecule does not appear to be proper in view of Applicants' disclosed commonality of operation, function and effect among donor dyes and among acceptor dyes.

The Examiner appears to have concluded that the species are distinct inventions as directed to patentably distinct species. The Examiner, however, does not specifically allege why the individual embodiments of the invention are distinct, separate inventions.

Applicants acknowledge that under MPEP, §808.02, in order to insist on a restriction, the Examiner must provide by appropriate explanation, one of the following:

(1) That the allegedly distinct species of the invention are categorized under separate classifications, demonstrating separate subject matter and therefore necessitating a separate search;

(2) That the species have a separate status in the art even though they are classified together, which may be shown by citing patents which are evidence of such separate status, and also a separate field of search; or

(3) That the separate species would require a separate field of search, even though they are classified together, because one of the distinct subjects would require a search in an area where no pertinent art to the other subjects exist.

The Examiner has provided no explanation as to why the species of the present invention are separate and distinct inventions meeting any of the above criteria. However, in an effort to advance prosecution of the present application, applicants make the following elections:

Applicants elect, with traverse, the peptide depicted in Figure 1B as the "specific modified protein", except that the Tyr shown at position 47 has been replaced with an amino acid analog. The donor dye molecule is attached to the side chain of the amino acid analog at position 47 *via* a semicarbazone linkage that links the donor dye molecule with the "modified protein".

With respect to the requirement for election of a specific "donor dye molecule", applicants elect, with traverse, fluorescein and its derivatives. For example, a semicarbazide derivative of fluorescein can be used to modify the side chain of the amino acid analog through a semicarbazone linkage, as depicted in Figure 8.

With respect to the Examiner's requirement to elect a specific "acceptor dye molecule", applicants elect, with traverse, rhodamine and its derivatives.

In view of the remarks above, Applicants respectfully request that the requirement for election of species be withdrawn and consideration of all of the claims on the merits be commenced.

Should the Examiner have any questions, the Examiner is respectfully invited to contact the undersigned agent at the telephone number set forth below.

Respectfully submitted,

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